IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF FLORIDA

BRITTANY BONGIOVANNI, *et al.*, Plaintiffs, v. LLOYD J. AUSTIN, III, in his official capacity as Secretary of Defense, *et al.*, Defendants.	)	Civil Action No. 3:22-CV-00237-MMH-MCR

DECLARATION OF COLONEL TONYA RANS

I, Colonel Tonya Rans, hereby state and declare as follows:

1. I am currently employed by the U.S. Air Force as the Chief, Immunization Healthcare Division, Defense Health Agency – Public Health Directorate, located in Falls Church, Virginia. I have held the position since June 2017. I am a medical doctor and have been board certified in Allergy/Immunology since 2008 and was a board certified Pediatrician from 2001-2015.

2. In my current role, my responsibilities include directing a responsive, evidence-based, patient-centered organization promoting optimal immunization healthcare for all DoD beneficiaries and those authorized to receive immunization from DoD. This includes assisting in policy development, providing implementation guidance and education, and engaging in clinical studies and research through clinical collaboration. The Defense Health Agency-Immunization Healthcare Division (DHA-IHD) routinely engages with the medical representatives from the military departments, U.S. Coast Guard, Joint Staff, Combatant Commands, and others to develop

standardized immunization implementation guidance in accordance with published policy for consistency across DoD where possible.

3. I am aware of the allegations set forth in the pleadings filed in this matter. This declaration is based on my personal knowledge, as well as information made available to me during the routine execution of my official duties.

Coronavirus Disease 2019 (COVID-19)

4. As part of my official duties, I served as a member of the COVID-19 Vaccine Distribution Operational Planning Team (OPT), which was directed to develop and implement DoD's COVID-19 Vaccine Distribution plan. The Coronavirus Task Force (CVTF) provided overarching guidance to the OPT. The OPT provided routine and ad hoc updates on COVID-19 vaccine deliveries, administration, and adverse events to the CVTF.

5. The virus that causes COVID-19 disease is SARS-CoV-2, a ribonucleic acid (RNA) virus from the Coronavirus family. Like any RNA virus, the SARS-CoV-2 virus mutates and evolves constantly and regularly as it infects and replicates in host cells. Mutations that are beneficial to the virus (i.e., make the virus more easily spread between hosts, evade the immune system) are integrated into the viral genome, thereby increasing "survival" and replication opportunity. This has been seen with the SARS-CoV-2 "Delta" variant, which is twice as contagious as previous variants.[1] However, not all mutations are beneficial to the virus – some can result in virus death and therefore do not infect the host. This is part of the normal biology cycle of all viruses.

[1] https://www.yalemedicine.org/news/5-things-to-know-delta-variant-covid, last accessed March 22, 2022.

6. The latest reports from the U.S. Centers for Disease Control and Prevention (CDC) indicate that the SARS-CoV-2 virus spreads when an infected person breathes out droplets and very small particles that contain the virus.[2] These droplets and particles can be inhaled by other people or land on their eyes, noses, or mouth. In some circumstances, viral particles may contaminate surfaces and then may be transmitted to another person by touching the contaminated surface followed by touching the eye, nose, or mouth. People who are closer than 6 feet from the infected person are most likely to get infected, especially in areas where there is poor ventilation.

7. COVID-19 disease can cause acute symptoms such as fever/chills, cough, shortness of breath, fatigue, muscle aches, headache, nausea, vomiting, diarrhea, loss of sense of smell or taste and/or sore throat. Symptoms appear 2-14 days (usually within 4-5 days) after viral exposure.[3] The infection can affect people in different ways: from asymptomatic, to limited and mild (for 2-3 days) to more severe (such as trouble breathing, chest pain, inability to think straight and inability to stay awake). Even with the availability of aggressive medical management and ventilator support in an intensive care setting for those with severe symptoms, hundreds of thousands with COVID-19 disease have died. As of March 16, 2022, CDC reports that over 79 million individuals in the U.S. have been diagnosed with COVID-19 disease, over 4.5 million have been hospitalized, and over 965,000 have died (approximately 1.5 in 500 in the total U.S. population of 330 million).[4] Per the CDC, the elderly and those with underlying medical history

[2] https://www.cdc.gov/coronavirus/2019-ncov/faq.html, last accessed March 24, 2022.

[3] https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html, last accessed March 24, 2022.

[4] https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covidview/index.html, last accessed March 24, 2022.

of cardiovascular disease, diabetes, chronic respiratory disease, smoking, being overweight or obese, pregnancy, immunocompromising conditions, or cancer are more likely to develop serious illness.[5] However, it is a misguided belief that those who are otherwise young and healthy could not develop severe, or even fatal, disease. During the acute infectious stage, the virus causes inflammatory cell death, resulting in the release of pro-inflammatory cytokines (proteins which are important in cell signaling). Pro-inflammatory cytokines can cause inflammatory cell death within multiple organs. Cell death releases cellular and viral fragments, which results in production and release of more inflammatory cytokines.[6] Disease progression can be curtailed by controlling the inflammatory process through immune system clearing of the virus. However, as depicted in the figure below, if the immune system is overwhelmed, either by viral immune evasive mechanisms or by an impaired host response, the pro-inflammatory cytokine process may continue unabated, causing increasingly severe disease such as acute respiratory distress syndrome (ARDS) and cytokine storm. Recognition of the viral and hyperinflammatory phases informs treatment strategies for those with COVID-19 disease. Therapies that directly target the SARS-CoV-2 virus are anticipated to have the greatest effect early in the course of the disease, whereas immunosuppressive/anti-inflammatory/antithrombotic (anti-clotting) therapies are likely to be more beneficial after COVID-19 has progressed to stages characterized by low oxygen levels such as seen in ARDS.[7]

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[5] https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html, last accessed March 23, 2022.

[6] Bordallo B, et al. Severe COVID-19: What Have We Learned With the Immunopathogenesis? *Adv Rheumatol* (2020) 60(1):50. doi: 10.1186/s42358-020-00151-7.

[7] https://www.covid19treatmentguidelines.nih.gov/management/clinical-management/, accessed March 23, 2022.

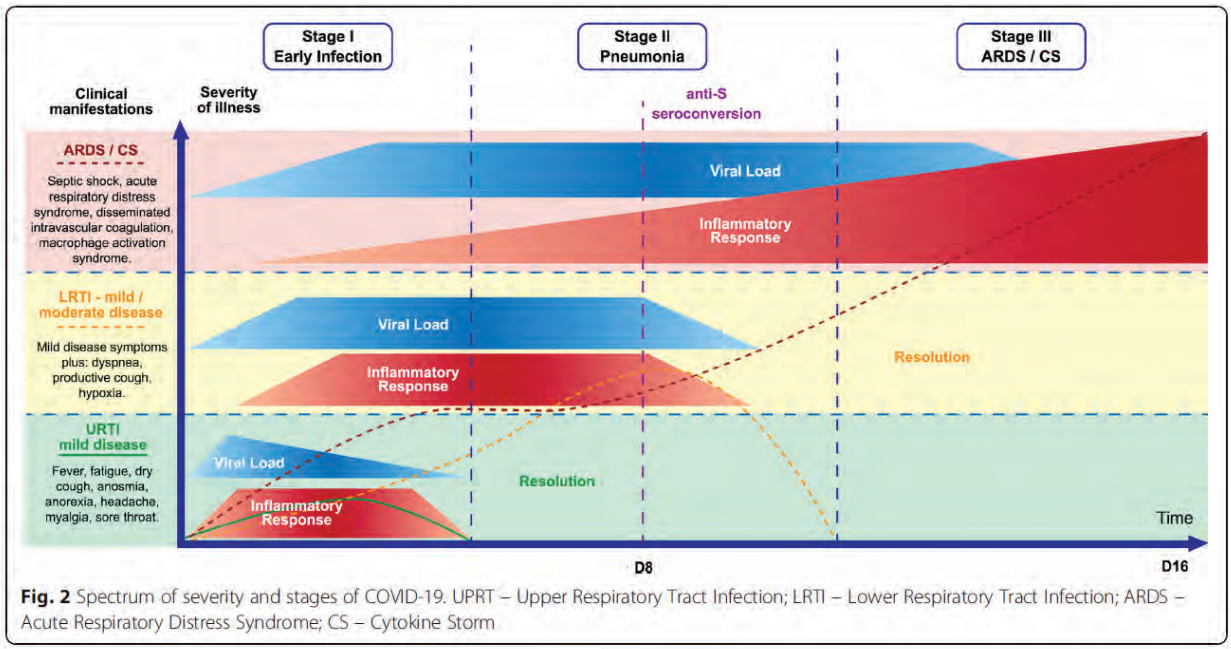

Fig. 2 Spectrum of severity and stages of COVID-19. UPRT – Upper Respiratory Tract Infection; LRTI – Lower Respiratory Tract Infection; ARDS – Acute Respiratory Distress Syndrome; CS – Cytokine Storm

8. The strongest recommendation for pre-exposure to COVID-19 disease remains vaccination, with highest level of evidence demonstrated through robust randomized control trials.[8] In contrast, the efficacy and/or outcomes of COVID-19 disease treatments are variable and depend on a person's underlying medical history, genetics, the COVID-19 variant causing disease, immune response, and interval between symptom onset and treatment initiation. Only one outpatient therapy, remdesivir, has received FDA approval to date. Other therapies are administered under a FDA emergency use authorization.[9] Just as it is acknowledged that there have been adverse events following COVID-19 vaccine receipt, it should also be understood that there are risks to COVID-19 disease treatment, even in those who are healthy enough to be managed in the outpatient setting. A non-exhaustive list of risks associated with COVID-19

[8] https://www.covid19treatmentguidelines.nih.gov/overview/prevention-of-sars-cov-2/, last accessed March 23, 2022.

[9] https://aspr.hhs.gov/COVID-19/Therapeutics/Documents/side-by-side-overview.pdf, last accessed March 23, 2022.

disease treatments includes cardiovascular and/or respiratory events, allergic reactions, and drug interactions. Further, some treatments must be administered shortly after diagnosis – within a matter of days – in order to be effective.[10]

9. Although most people with COVID-19 are better within weeks of illness, some people experience post-COVID-19 conditions (aka long/long-haul COVID, Postacute Sequelae of COVID-19 (PASC), long-term effects of COVID, or chronic COVID). Post-COVID-19 conditions include a wide range of new, returning, or ongoing health problems four or more weeks after infection. Those who were asymptomatic during their COVID-19 infection may still develop post-COVID-19 conditions. One systematic review assessing short and long-term rates of long-COVID in more than 250,000 COVID-19 survivors from 57 studies with an average age of 54 years demonstrated that more than 50% of these COVID-19 survivors continued to have a broad range of symptoms six months after resolution of the acute COVID-19 infection, of which the most common were functional mobility impairments, respiratory abnormalities, and mental health disorders.[11] Another study comparing outcomes in patients referred to outpatient rehabilitation clinics after COVID-19 reported poorer general, mental, and physical health and functioning compared with patients with no previous diagnosis of COVID-19 referred for cancer rehabilitation. Those referred for rehabilitation following COVID-19 were more likely to be male, younger, and employed.[12] A study assessing clinical patterns and recovery time from

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[10] *Id.*

[11] Groff, et al, *JAMA Network Open*, Short-term and Long-term Rates of Postacute Sequelae of SARS-CoV-2 Infection, https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2784918.

[12] Rogers-Brown JS, et al. CDC Morbidity and Mortality Weekly Report, Vol 70(27) 9 July 2021 https://www.cdc.gov/mmwr/volumes/70/wr/pdfs/mm7027a2-H.pdf.

COVID-19 illness in 147 international-level Paralympic and Olympic athletes showed that 86% had symptoms lasting ≤ 28 days, whereas 14% had symptoms of longer duration. In both groups, fatigue, dry cough, and headache were the predominant symptoms.[13] A recent study, conducted within the Department of Veterans Affairs, described long-term cardiovascular outcomes of 153,760 people with COVID-19 who survived the first 30 days after infection as compared with controls.[14] They provided evidence that, beyond the first 30 days of infection, people with a history of COVID-19 exhibited "increased risks and 12-month burdens of incident cardiovascular diseases, including cerebrovascular disorders (i.e. stroke), dysrhythmias (abnormal heart rhythms), inflammatory heart disease (i.e. myocarditis, pericarditis), ischemic heart disease (decreased blood flow to the heart), heart failure, thromboembolic disease (blood clots that can break loose and occlude a blood vessel), and other cardiac disorders." Of all cardiovascular diagnoses studied, the burdens of atrial fibrillation (AF) and heart failure (HF) were greatest. Risks of all cardiovascular disorders increased with severity of the acute COVID illness, with patients who required intensive care having particularly high risk. The authors report that the risks were evident regardless of age, race, sex, and other cardiovascular risk factors, including obesity, hypertension (high blood pressure), diabetes, chronic kidney disease, and hyperlipidemia (high cholesterol); they were also evident in people without any cardiovascular disease before exposure to COVID-19, "providing evidence that these

[13] Hull JH, et al. Clinical patterns, recovery time and prolonged impact of COVID-19 illness in international athletes: the UK experience. *Br J Sports Med* 2021;0:1-8. Doi 10.1136/bjsports-2021-104392.

[14] Xie, Y., Xu, E., Bowe, B. *et al.* Long-term cardiovascular outcomes of COVID-19. *Nat Med* (2022). https://doi.org/10.1038/s41591-022-01689-3.

cardiovascular risks might manifest even in people at low risk for cardiovascular disease."[15] An additional study of patients enrolled in Veterans Affairs system found an increased risk of diabetes among those who had tested positive for COVID-19 when compared to contemporary and historical control groups. The review of millions of records found that people who had been diagnosed with COVID-19 were 46% more likely to develop Type 2 diabetes for the first time.[16]

COVID-19 Impacts on the Force

10. Infectious diseases have been the single greatest threat to the health of those involved in military operations. As the standard military unit shrinks and becomes more mobile to rapidly respond to global threats, any decrease in personal or unit readiness can significantly decrease operational efficiency and result in military ineffectiveness. Similar to other viruses, the SARS-CoV-2 virus can be easily transmitted to others prior to symptom development and therefore may infect significant numbers before being identified. DoD personnel, including service members, especially those in an operational setting (such as those working on ships, submarines, or engaged in the operation of aircraft and vehicles; those deployed to austere environments; or those engaged in routine field training and airborne exercises), work in environments where duties may limit the ability to strictly comply with mitigation measures such as wearing a face mask, avoiding crowded areas, maintaining physical distancing of at least 6 feet, increasing indoor ventilation, maintaining good hand hygiene, and quarantining if in close contact

[15] *Id.*

[16] Xie Y and Al-Aly Z. Risks and burdens of incident diabetes in long COVID: a cohort study https://www.thelancet.com/journals/landia/article/PIIS2213-8587(22)00044-4/fulltext, last accessed March 23, 2022.

with a COVID-19 case.[17] Therefore, upon exposure, these individuals may be at higher risk to be diagnosed with COVID-19 compared to those who can robustly maintain all recommended mitigation strategies. Further, although the elderly population and those with medical conditions are more likely to have severe disease, otherwise healthy Service members have developed "long-haul" COVID-19, potentially impacting their long-term ability to perform their missions. Data presented from DoD's COVID-19 registry has demonstrated that of 111,767 active duty service members who had COVID-19 disease between February 1, 2020 to August 12, 2021, 37,838 (33.9%) had diagnoses for conditions requiring a healthcare visit 30-180 days following their illness, the most common being joint/muscle pain (15,614 or 14%) followed by chest pain/cough (7,887 or 7.1%). In comparison, only 8.3% and 1.81%, respectively, of active duty service members had a healthcare visit for those diagnoses 30-180 days after vaccination. All diagnoses associated with "Long-COVID-19 Syndrome" were found to be more common after COVID-19 disease than after COVID-19 vaccination. Some service members have unfortunately succumbed to the disease, as described further below. Service members and federal civilian employees are the military's most valuable asset; without a medically ready force and ready medical force, the military mission is at high risk of failure. Recommendations from evidence-based medicine must remain the core approach to medical readiness. These evidence-based recommendations will continue to be updated as our understanding of the disease, complications, and impact from vaccination continues to evolve.

[17] The U.S. military's rapid response to the crisis in Ukraine and the surrounding areas serves as a prime example of the difficulty in not only predicting where and when service members will be required to serve, but also of the challenges in preventing the spread of COVID-19 and other diseases in undeveloped and austere environments. *See, e.g.,* https://www.dvidshub.net/image/7065893/82nd-airborne-division-place-their-equipment-inside-tent-they-settle-their-new-location, last accessed March 23, 2022.

11. Between February 2020 and February 2022, there were 373,750 new and repeat cases of COVID-19 among active duty service members (see Table below). The largest monthly peak in cases occurred in January 2022, with 119,943 cases identified (see Figure below). The percentage of cases that were hospitalized was highest at the start of the pandemic and trended downward through January 2021. The percentage of hospitalized cases then increased from 0.9% in January 2021 to 2.1% in May 2021 and 2.0% in July 2021, and decreased to 0.5% in December 2021. The percentage of hospitalized cases remained low at 0.3% in January 2022 and 0.4% in February 2022. However, this recent trend should be interpreted with caution due to data lags. In total, 31 active duty service members have died from COVID-19 as of the end of February 2022. The number of active duty service members who died from COVID-19 remained very low throughout the first year of the pandemic, with a slight increase in the numbers of deaths occurring between December 2020 and February 2021, and a greater increase occurring between August and October 2021, coinciding with the increased spread of the Delta variant. More than one-half of the 31 deaths in active duty service members occurred between August and October 2021 (n=17). The most recently reported active duty service member death occurred in November 2021.

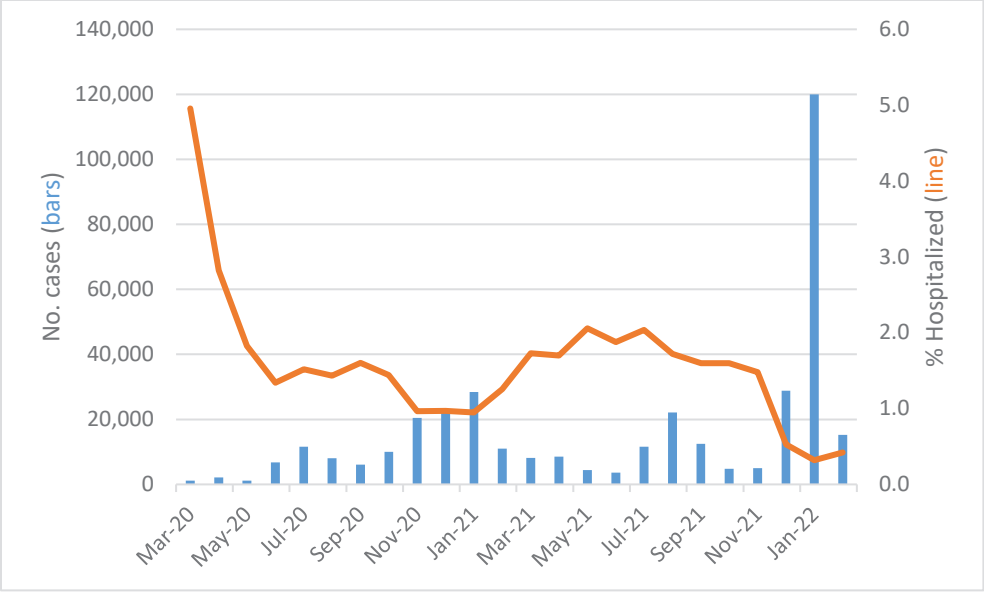
Table. COVID-19 cases, hospitalizations, and deaths among active duty service members, February 2020 - February 2022

	No. cases	No. hospitalizations	% hospitalizations	No. deaths
Feb-20	7	2	28.6	0
Mar-20	1,150	57	5.0	0
Apr-20	2,127	60	2.8	1
May-20	1,204	22	1.8	0
Jun-20	6,791	91	1.3	0

Jul-20	11,609	176	1.5	0
Aug-20	8,013	115	1.4	0
Sep-20	6,120	98	1.6	0
Oct-20	10,066	145	1.4	1
Nov-20	20,433	197	1.0	0
Dec-20	22,137	215	1.0	2
Jan-21	28,429	270	0.9	2
Feb-21	10,987	138	1.3	5
Mar-21	8,150	141	1.7	0
Apr-21	8,589	146	1.7	1
May-21	4,426	91	2.1	0
Jun-21	3,572	67	1.9	0
Jul-21	11,593	236	2.0	1
Aug-21	22,094	380	1.7	5
Sep-21	12,462	199	1.6	6
Oct-21	4,816	77	1.6	6
Nov-21	4,997	74	1.5	1
Dec-21	28,797	151	0.5	0
*Jan-22	119,943	383	0.3	0
*Feb-22	15,238	64	0.4	0

*Hospitalization and death data not complete due to data lags

Figure. COVID-19 cases among active duty service members and percentage of cases that were hospitalized, March 2020 – February 2022



Note: February 2020 is not shown due to the very small number of cases. Hospitalization data for January - February 2022 not complete due to data lags

12. The DoD regularly updates its information concerning the number of vaccinations provided by DoD, the vaccination of the force, and health impact of those who developed COVID-19 infections.[18] As depicted below, data through March 18, 2022 demonstrated that of the 610,333 COVID-19 cases within the DoD, 6,261 individuals were hospitalized and 682 have died, including 94 military service members (service members include Active Duty, Reserves, and National Guard personnel). In both the civilian sector and in the military, the overwhelming majority of individuals hospitalized or who died were unvaccinated or not fully vaccinated.

[18] https://www.defense.gov/Spotlights/Coronavirus-DOD-Response/, last accessed March 23, 2022.

DOD COVID-19 CUMULATIVE TOTALS

	Cases	Hospitalized	Recovered	Deaths
Military	392,353	2,592	378,988	94
Civilian	121,091	2,358	106,231	414
Dependent	61,357	552	55,110	35
Contractor	35,532	759	32,406	139
Total	610,333	6,261	572,735	682

13. The bed capacity at DoD's military medical treatment facilities (MTFs) has generally followed local civilian hospital utilization, with some MTFs having high admission rates and a need to temporarily curtail medical services. Throughout the pandemic, the National Guard has been called on extensively to provide medical support to the civilian population. During the winter months, DoD had increasingly been deploying military doctors, nurses, paramedics and other personnel to U.S hospitals to assist in preventing the country's medical system from collapsing from demand.

Vaccine Impacts

14. Immunization is a global health and development success story, saving millions of lives across the age spectrum annually from illness, chronic conditions, and potentially death. Immunizations provide benefit at both the individual and community level. First, by stimulating an active immune response, vaccinated individuals are largely protected from the disease of concern. Second, when a high proportion of individuals are immune (i.e., herd immunity) human-to-human transmission is disrupted, thereby protecting those who remain susceptible (i.e., those who may not be able to receive a vaccine or do not mount an adequate antibody response). Disease

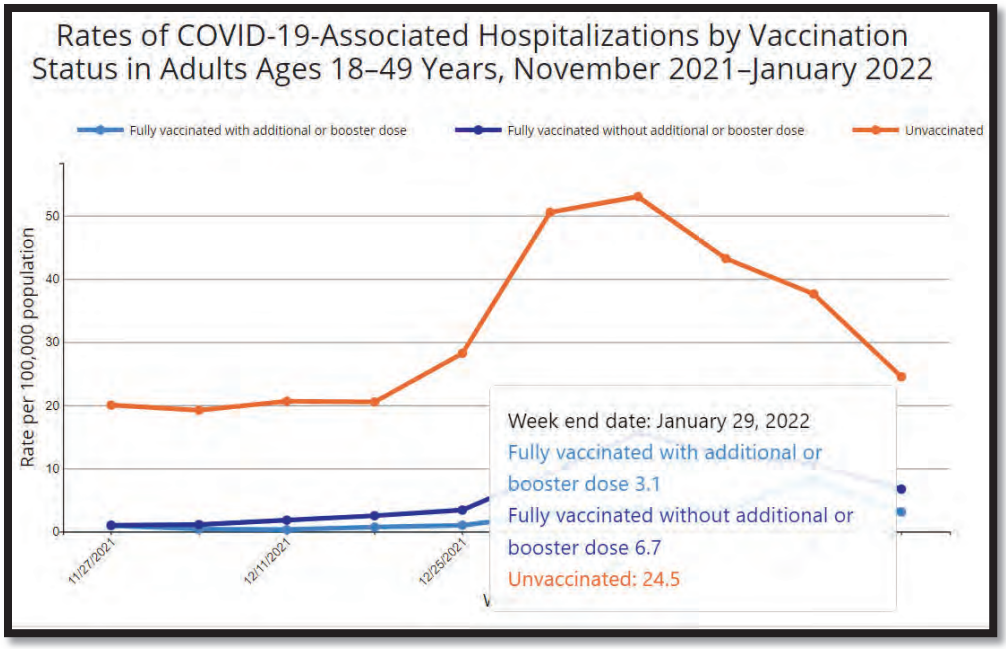
prevention through immunization also mitigates the need for pharmacologic treatment, reducing the risk of drug-drug interactions or adverse reactions to the treatment. .

15. A key component of primary health care, the U.S. Food and Drug Administration (FDA) provides regulatory allowance for immunizations and has licensed vaccines for over 20 different infectious diseases. The Advisory Committee on Immunization Practices (ACIP), an advisory committee of the CDC, develops recommendations on how to use vaccines to control diseases in the United States. The military also maintains awareness, surveillance, and provides guidance to DoD personnel and beneficiaries on vaccine-preventable diseases in the global setting.

16. According to the CDC, over 558 million doses of COVID-19 vaccine have been given in the United States from December 14, 2020, through March 21, 2022.[19] Evidence consistently shows that the incidence of COVID-19-associated, hospitalizations and deaths are higher in unvaccinated than vaccinated persons. During the week ending January 29, 2022, the rate of COVID-19 associated hospitalization was 3.1 per 100,000 in those who were fully vaccinated with an additional or booster dose; 6.7 per 100,000 in those who were fully vaccinated without an additional or booster dose; and 24.5 per 100,000 in those who were unvaccinated.[20]

[19] https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/safety-of-vaccines.html, last accessed March 23, 2022.

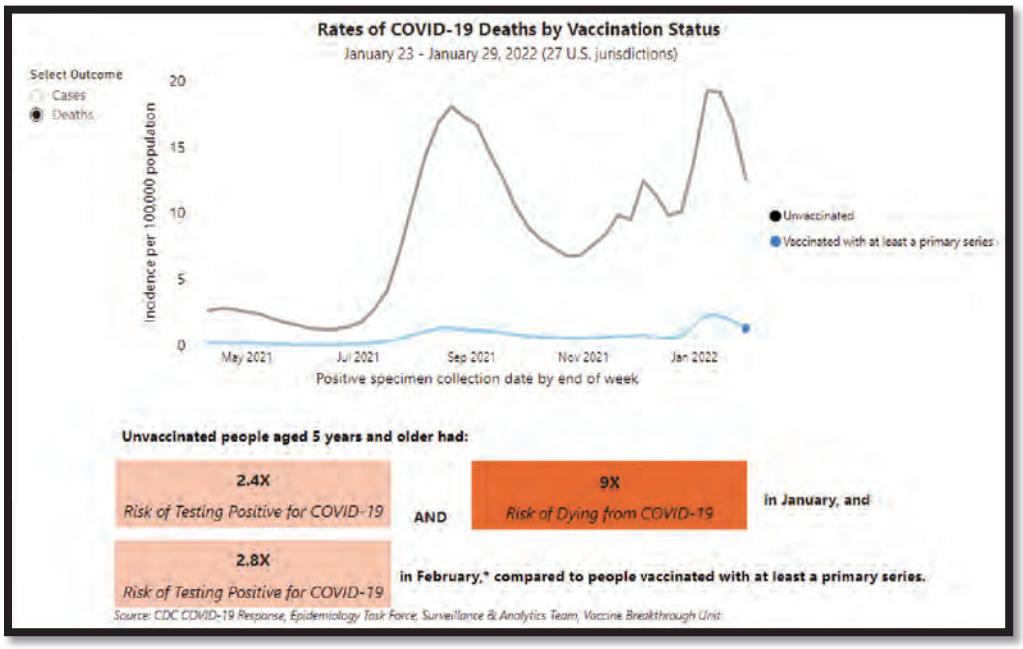
[20] https://covid.cdc.gov/covid-data-tracker/#covidnet-hospitalizations-vaccination, last accessed March 23, 2022.

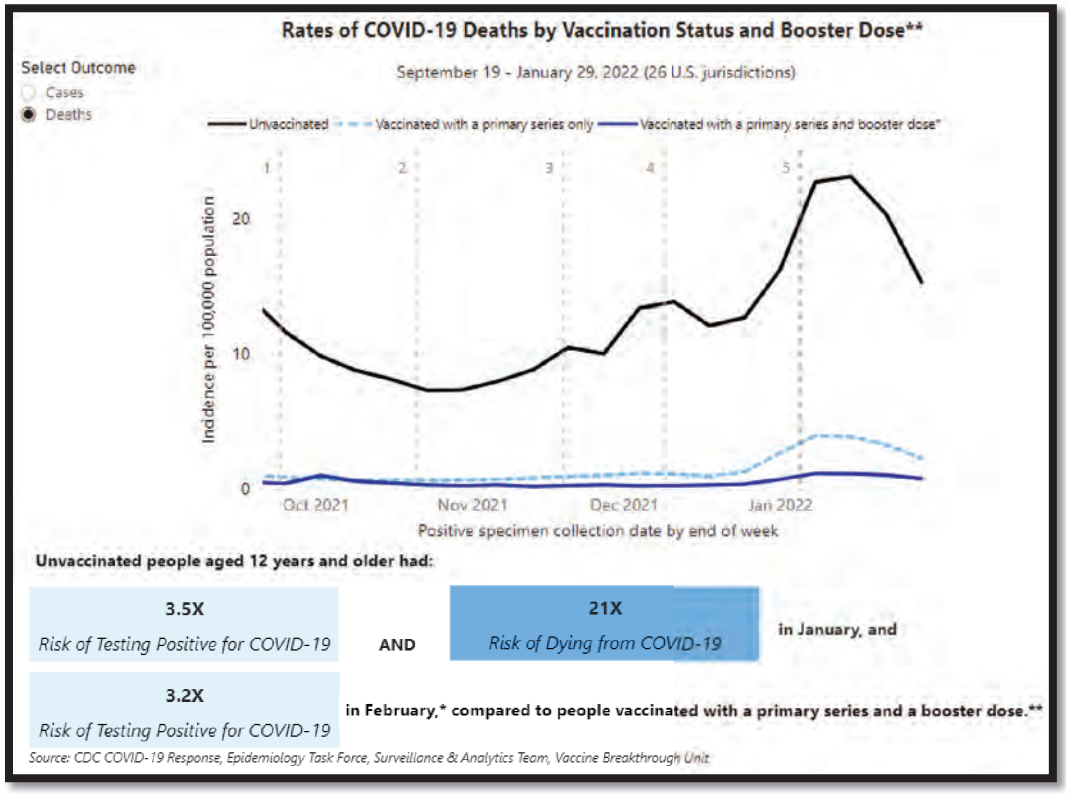


According to CDC data in January 2022, unvaccinated persons 5 years of age and older had a 2.4 times greater risk of testing positive for COVID-19 and a 9 times greater risk of dying from COVID-19 compared to fully vaccinated individuals, and unvaccinated persons 18 years of age and older had a 3.5 times greater risk of testing positive for COVID-19 and 21 times greater risk of dying from COVID-19 compared to fully vaccinated adults with a booster dose.[21] In February 2022, unvaccinated adults aged 5 years and older had a 2.8 times greater risk of testing positive for COVID-19 compared to people vaccinated with at least the primary series and a 3.2 times greater risk of testing positive for COVID-19 compared to fully vaccinated adults with booster doses.[22]

[21] https://covid.cdc.gov/covid-data-tracker/#rates-by-vaccine-status, last accessed March 23, 2022.

[22] *Id.*


Rates of COVID-19 Deaths by Vaccination Status
January 23 - January 29, 2022 (27 U.S. jurisdictions)
Select Outcome
Cases
Deaths
Incidence per 100,000 population
20
15
10
5
0
May 2021
Jul 2021
Sep 2021
Nov 2021
Jan 2022
Positive specimen collection date by end of week
Unvaccinated
Vaccinated with at least a primary series
Unvaccinated people aged 5 years and older had:
2.4X
Risk of Testing Positive for COVID-19
AND
9X
Risk of Dying from COVID-19
in January, and
2.8X
Risk of Testing Positive for COVID-19
in February,* compared to people vaccinated with at least a primary series.
Source: CDC COVID-19 Response, Epidemiology Task Force, Surveillance & Analytics Team, Vaccine Breakthrough Unit


Rates of COVID-19 Deaths by Vaccination Status and Booster Dose**
September 19 - January 29, 2022 (26 U.S. jurisdictions)
Select Outcome
Cases
Deaths
Unvaccinated
Vaccinated with a primary series only
Vaccinated with a primary series and booster dose"
Incidence per 100,000 population
20
10
0
Oct 2021
Nov 2021
Dec 2021
Jan 2022
Positive specimen collection date by end of week
Unvaccinated people aged 12 years and older had:
3.5X
Risk of Testing Positive for COVID-19
AND
21X
Risk of Dying from COVID-19
in January, and
3.2X
Risk of Testing Positive for COVID-19
in February,* compared to people vaccinated with a primary series and a booster dose.**
Source: CDC COVID-19 Response, Epidemiology Task Force, Surveillance & Analytics Team, Vaccine Breakthrough Unit

17. As of March 23, 2022, DoD immunization sites have administered over 7.9 million doses of COVID-19 vaccine. Adverse events temporally associated with vaccine administration are centrally captured by CDC and FDA's Vaccine Adverse Event Reporting System (VAERS) through passive surveillance, meaning that information is voluntarily reported by health care providers and the public. VAERS is not designed to determine whether a vaccine caused a health issue of concern, but it is useful for detecting unexpected patterns of adverse event reporting that might indicate a possible safety problem with a vaccine. As of March 11, 2022, a total of 8,456 unique VAERS reports (approximately 11 VAERS reports/10,000 doses administered) were submitted by DoD beneficiaries or those authorized to receive vaccine from DoD. Note that the number of VAERS reports/10,000 doses administered for DoD beneficiaries is likely to be lower, as the denominator does not take into account beneficiaries who receive vaccine in the civilian sector though DoD would still receive their VAERS report if the submitter indicated military affiliation. Additionally, individuals who had an adverse event but did not submit a VAERS would not be known and therefore would not be counted. It must be stressed that a VAERS submission to the CDC does not mean that the vaccine of concern caused or contributed to the medical issue reported.

18. The DoD has received hundreds of thousands of Pfizer-BioNTech BLA-manufactured, EUA-labeled COVID-19 vaccine doses and continues to use them.

19. Approach to immunizations within DoD are outlined in DoD Instruction 6205.02, "DoD Immunization Program" dated June 19, 2019, which states that it is DoD policy that all DoD personnel and other beneficiaries required or eligible to receive immunizations will be offered

immunizations in accordance with recommendations from the CDC and its ACIP. Army Regulation 40-562, Navy Bureau of Medicine and Surgery Instruction 6230.15B, Air Force Instruction 48-110_IP, Coast Guard Commandants Instruction M6230.4G, "Immunizations and Chemoprophylaxis for the Prevention of Infectious Diseases," October 7, 2013, further states the Military Service policy concerning immunizations follows the recommendations of the CDC, ACIP, and the prescribing information on the manufacturer's package inserts, unless there is a military-relevant reason to do otherwise. This document also describes general examples of medical exemptions, which include "evidence of immunity based on serologic tests, documented infection, or similar circumstances." Some interpret this as a diagnosis of COVID-19 disease and/or results of a COVID-19 serologic test means that a medical exemption should be granted. However, of significance is the phrase "evidence of immunity." CDC defines immunity as "protection from an infectious disease. If you are immune to a disease, you can be exposed to it without becoming infected."[23] There are two major types of testing available for COVID-19: diagnostic tests, which assess for current infection, and antibody tests, which assess for antibody production, which is indicative of past infection and (in some tests) a history of vaccination. The FDA states, "Antibody tests should not be used to diagnose a current SARS-CoV-2 infection or COVID-19 and, at this time, should also not be used to check for immunity. More research is needed to determine what, if anything, antibody tests can tell us about a person's immunity."[24] As described below, lab tests for serology also state that it is unclear at this time if a positive antibody

[23] https://www.cdc.gov/healthyschools/bam/diseases/vaccine-basics.htm, last accessed March 24,, 2022.

[24] https://www.fda.gov/consumers/consumer-updates/coronavirus-disease-2019-testing-basics, last accessed March 24, 2022.

result infers immunity against future COVID-19 infection. Therefore, given the scientific evidence available, a medical exemption based on the history of COVID-19 disease or serology results does not meet "evidence of immunity." The presence of antibodies is not the same thing as being immune.

20. The CDC states that "COVID-19 vaccination is recommended for everyone aged 5 years and older, regardless of a history of symptomatic or asymptomatic SARS-CoV-2 infection. This includes people with prolonged post-COVID-19 symptoms and applies to primary series doses and booster doses. This recommendation also applies to people who experience SARS-CoV-2 infection before or after receiving any COVID-19 dose… Current evidence demonstrates a robust immune response to vaccination after infection, but information is lacking about whether and how the amount of time since infection affects the immune response to vaccination. Growing epidemiologic evidence from adults and adolescents indicates that vaccination following infection further increases protection from subsequent infection, including in the setting of increased circulation of more infectious variants. Viral testing to assess for acute SARS-CoV-2 infection or serologic testing to assess for prior infection is not recommended for the purpose of vaccine decision-making."[25]

21. Further, CDC states "antibody testing is not currently recommended to assess the need for vaccination in an unvaccinated person or to assess immunity to SARS-CoV-2 following COVID-19 vaccination. If antibody testing was done, vaccination with the primary series, an additional dose, or a booster dose should be completed as recommended regardless of the antibody test result. SARS-CoV-2 antibody tests currently authorized under an Emergency Use

[25] https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fvaccines%2Fcovid-19%2Finfo-by-product%2Fclinical-considerations.html, last accessed March 24, 2022

Authorization have variable performance characteristics and limitations. Furthermore, serologic correlates of protection have not been established and antibody testing does not evaluate the cellular immune response."[26]

22. Although natural infection for some diseases, in some cases, can result in long-standing immunity (e.g., measles), there is risk of untoward outcomes from the disease itself, which can be chronic or even fatal. Examples include Pneumonia or invasive group B Strep from chickenpox, meningitis or epiglottitis from *Haemophilis influenza* type B, birth defects from rubella, liver cancer from Hepatitis B, and death from measles.

23. Examples of natural infections that do not mount long-standing immunity include, in addition to COVID-19, Influenza, Respiratory Syncytial Virus, Malaria, Whooping cough, and rotavirus. In other words, re-infection is possible. Multiple serotypes of a pathogen like influenza, pneumococcus, and possibly with the COVID-19 variants, also make determination of a protective serologic level more difficult, especially to say there is lifelong immunity.

24. "Herd immunity" is an epidemiologic concept that explains how a community may be protected from an infectious disease that is human-to-human transmitted.[27]-[28] Herd immunity can be achieved through vaccination or through natural infection, if enough individuals 1) survive the disease and 2) mount a life-long immune response. Safe and effective vaccines are

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[26] https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fvaccines%2Fcovid-19%2Finfo-by-product%2Fclinical-considerations.html, last accessed March 24, 2022.

[27] Desai AN, Majumder MS. What Is Herd Immunity? *JAMA*. 2020;324(20):2113. doi:10.1001/jama.2020.20895

[28] McDermott A. Core Concept: Herd immunity is an important-and often misunderstood-public health phenomenon. *Proc Natl Acad Sci U S A*. 2021;118(21):e2107692118. doi:10.1073/pnas.2107692118

unequivocally considered the safer approach to a vaccine-preventable disease as compared to the unpredictable response that an individual may have to exposure to disease, as described above. When a large proportion of a community is immune, vulnerable members of the community are indirectly protected because their chance of infection exposure is very low. Herd immunity does not eliminate risk, but the phenomenon means that population risk is greatly reduced. Herd immunity is only possible when humans are the only source of infection transmission, when immunity can be clearly established to prevent lifelong infection and transmission, and when an adequate proportion of the population can safely develop immunity to protect all others. Measles (rubeola virus infection) is a classic example of the successful application of the concept of herd immunity. It is important to recognize that there is no disease where a vaccination program would cease once a certain level of immunity is reached, unless the disease is considered eradicated (i.e. smallpox in humans). The CDC recommends children continue to receive routine immunizations for diseases that we have not seen in this country for many years (i.e., polio) or rarely see (i.e. epiglottitis from *Haemophilus influenza*) so the vaccine preventable disease does not resurge. The Department of Defense vaccine program follows these same principles.

25. The percentage of the population needing to be immune to drive herd immunity varies from disease to disease. Generally, the more contagious a disease is, the greater proportion of the population needs to be immune to stop its spread. For example, with regards to the highly contagious measles disease, approximately 95% immunity within a population is needed to interrupt the chain of transmission. When the immunity levels of a population falls, local outbreaks can, and have, occurred. In 2019, 1,282 individual cases of measles were confirmed in 31 states,

the highest level since 1992. The majority of those cases were among those who were not vaccinated.[29,30]

26. The herd immunity threshold – the level above which the spread of disease will decline – is currently unknown for COVID-19. As described above, in order to interpret an antibody response as it pertains to immunity, a correlate of protection (i.e. what antibody result do I need to be considered immune?) must be determined and validated. No FDA antibody test has validated a correlate of protection at this time and none of them are licensed. Nonetheless, it is generally agreed that the more severe the COVID-19 disease is in an individual, the more antibodies a survivor would produce and therefore likely would have a higher degree of protection and possibly be protected longer than those who are asymptomatic or with mild symptoms.

27. Those who receive the COVID-19 vaccine contribute to the information available from studying the outcomes from 558 million doses administered in the US and over the 11.14 billion doses administered globally.[31] Responses to vaccination are more consistent and there is minimal risk compared to the potential long-term complications and treatments needed to treat COVID-19 disease. Although breakthrough infections do occur depending on the circulating variant and the longer the interval from vaccination, vaccines (especially when a booster is also received) remain highly effective in preventing hospitalizations and death.[32]

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[29] https://www.cdc.gov/measles/cases-outbreaks.html, last accessed March 24, 2022.

[30] https://www.cdc.gov/mmwr/volumes/68/wr/pdfs/mm6840e2-H.pdf, last accessed March 24, 2022.

[31] https://ourworldindata.org/covid-vaccinations?country=OWID_WRL, last accessed March 24, 2022.

[32] Ferdinands JM, et al. Waning 2-Dose and 3-Dose Effectiveness of mRNA Vaccines Against COVID-19-Associated Emergency Department and Urgent Care Encounters and Hospitalizations Among Adults During Periods of Delta and Omicron Variant Predominance –

28. In October 2021, prior to the presentation of the Omicron variant, the newest SARS-CoV-2 variant of concern, CDC summarized a review of 96 peer-reviewed and preprint publications, providing an overview of current scientific evidence regarding infection-induced immunity.[33] Key findings include the following:

- Available evidence shows that fully vaccinated individuals and those previously infected with SARS-CoV-2 each have a low risk of subsequent infection for at least 6 months. Data are presently insufficient to determine an antibody titer threshold that indicates when an individual is protected from infection. At this time, there is no FDA-authorized or approved test that providers or the public can use to reliably determine whether a person is protected from infection.
    - The immunity provided by vaccine and prior infection are both high but not complete (i.e., not 100%).
    - Multiple studies have shown that antibody titers correlate with protection at a population level, but protective titers at the individual level remain unknown.
    - Whereas there is a wide range in antibody titers in response to infection with SARS-CoV-2, completion of a primary vaccine series, especially with mRNA vaccines, typically leads to a more consistent and higher-titer initial antibody response.
    - For certain populations, such as the elderly and immunocompromised, the levels of protection may be decreased following both vaccination and infection.

VISION Network, 10 States, August 2021-January 2022, https://www.cdc.gov/mmwr/volumes/71/wr/mm7107e2.html, last accessed March 24, 2022 .

[33] https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/vaccine-induced-immunity.html, last accessed March 24, 2022.

- Current evidence indicates that the level of protection may not be the same for all viral variants.
- The body of evidence for infection-induced immunity is more limited than that for vaccine-induced immunity in terms of the quality of evidence (e.g., probable bias towards symptomatic or medically-attended infections) and types of studies (e.g., observational cohort studies, mostly retrospective versus a mix of randomized controlled trials, case-control studies, and cohort studies for vaccine-induced immunity). There are insufficient data to extend the findings related to infection-induced immunity at this time to persons with very mild or asymptomatic infection or children.

29. Debate continues about whether natural immunity versus vaccine-induced immunity is more protective against breakthrough infections (a reinfection in someone who was previously infected versus an infection in a previously not infected individual who was fully immunized). A frequently cited, though not peer-reviewed, retrospective study from Israel found that the rates of SARS-CoV-2 breakthrough infections in vaccinated individuals, while very low (highest rate = 1.5%) were 13 times higher than the rates of reinfection and hospitalization in previously infected individuals.[34] These findings have not been reproduced in a peer-reviewed or prospective publication. However, an observational study,[35] also out of Israel, compared adverse events in Pfizer-BioNTech vaccinated versus unvaccinated individuals in addition to

[34] https://www.medrxiv.org/content/10.1101/2021.08.24.21262415v1, last accessed March 24,2022.

[35] Barda N, et al. Safety of the BNT162b2 mRNA COVID-19 Vaccine in a Nationwide Setting N Engl J Med 2021; 385:1078-1090.

those who had a history of COVID-19 disease versus those who did not. As previously identified in multiple studies, vaccination with an mRNA vaccine like Pfizer-BioNTech was associated with an elevated risk of myocarditis compared to those unvaccinated (risk difference 2.7 events/100,000 people). However, when assessing the relative risk in those with a history of COVID-19 disease with those who did not have disease, the risk of myocarditis was substantially higher in those who had COVID-19 disease (risk difference of 11 events/100,000 persons). The risk difference is calculated as the difference between the observed risks in the two groups.

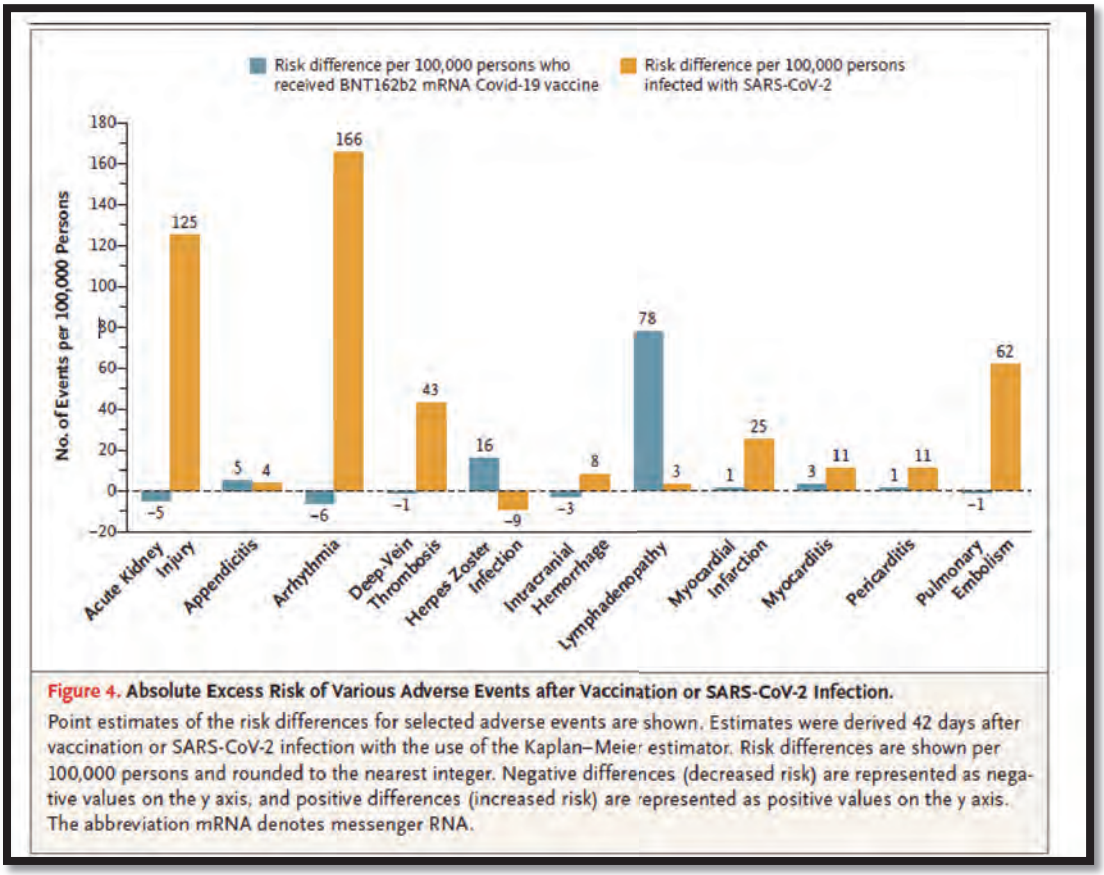

Figure 4. Absolute Excess Risk of Various Adverse Events after Vaccination or SARS-CoV-2 Infection.
Point estimates of the risk differences for selected adverse events are shown. Estimates were derived 42 days after vaccination or SARS-CoV-2 infection with the use of the Kaplan–Meier estimator. Risk differences are shown per 100,000 persons and rounded to the nearest integer. Negative differences (decreased risk) are represented as negative values on the y axis, and positive differences (increased risk) are represented as positive values on the y axis. The abbreviation mRNA denotes messenger RNA.

The Omicron variant

30. On November 26, 2021, the World Health Organization (WHO) designated the Omicron variant (Pango lineage B.1.1.529), first identified in November 2021 in Botswana and South Africa, a "variant of concern" upon recommendations of the Technical Advisory Group on SARS-CoV-2 Virus Evolution, which assesses if specific mutations and combinations of mutations alter the behavior of the virus.[36] The United States designated Omicron as a variant of concern on November 30, 2021, and following first detection in the United States on December 1, 2021, it has been found to spread more easily than the original and Delta variants.[37] Those infected with the Omicron variant in South Africa were initially reported in the media as not having severe outcomes and therefore concluding that this would be a "mild" variant. In attempt to address that misconception, on January 6, 2022, Dr. Tedros Adhanom Ghebreyesus, the WHO Director-General, stated that "while Omicron does appear to be less severe compared to Delta, especially in those vaccinated, it does not mean it should be categorized as 'mild'. Hospitals are becoming overcrowded and understaffed, which further results in preventable deaths from not only COVID-19 but other diseases and injuries where patients cannot receive timely care. First-generation vaccines may not stop all infections and transmission but they remain highly effective in reducing hospitalization and death from this virus."[38]

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[36] https://www.who.int/news/item/26-11-2021-classification-of-omicron-(b.1.1.529)-sars-cov-2-variant-of-concern, last accessed March 24, 2022.

[37] https://www.cdc.gov/coronavirus/2019-ncov/variants/omicron-variant.html, last accessed March 24, 2022.

[38] https://twitter.com/WHO/status/1479167003109859328, posted January 6, 2022.

31. The Omicron variant has approximately 32 mutations on the spike (S) protein with approximately 15 of the 32 occurring within the receptor binding domain (RBD). The RBD is what the virus uses to bind to our cells and initiate viral infection process. Antibodies produced from previous infection or vaccination, as well as the monoclonal antibodies (mAb) given to treat those infected, target the RBD. The degree to which antibodies bind or "neutralize" the virus, determines the degree of resultant illness – the better antibodies bind, the less likely a person will become ill. This is why any mutation on the S protein RBD would cause concerns about the efficacy of existing vaccines, antibodies produced from previous infection, and the mAb given to treat people in preventing Omicron infection. One study, using an artificial intelligence (AI) model, revealed that "Omicron may be over 10 times more contagious than the original virus or about 2.8 times as infectious as the Delta variant."[39]

32. Multiple investigators turned their attention to assessing the effectiveness of antibodies following COVID-19 disease and current vaccines against Omicron. One study assessed the neutralization of 9 monoclonal antibodies (mAb), sera from 34 COVID-19 vaccine (Pfizer or Astra Zeneca) primary series recipients who had not previously been infected, sera from 20 recipients who had received a Pfizer-BioNTech booster dose, and sera from 40 convalescent sera (blood serum obtained from individuals who had a history of infection) donors, 22 of whom had also been vaccinated.[40] The better the neutralization, the better the protection. Results showed that the Omicron variant was totally or partially resistant to neutralization by all mAbs tested. Sera

[39] Chen J, et al. Omicron Variant (B.1.1.529): Infectivity, Vaccine Breakthrough, and Antibody Resistance J. Chem. Inf. Model. 2022, 62, 2, 412-422 https://doi.org/10.1021/acs.jcim.1c01451.

[40] Planas, D. et al. Considerable escape of SARS-CoV-2 Omicron to antibody neutralization. *Nature* https://doi.org/10.1038/s41586-021-04389-z (2021).

from those vaccinated, sampled 5 months after being fully vaccinated, had limited inhibition of the Omicron variant. Blood sera from those with a history of COVID-19 disease demonstrated no or low neutralizing activity against Omicron. Those who received a booster COVID-19 vaccine dose did generate an anti-Omicron neutralizing response, though lower than what has been seen against the Delta variant. A second study[41] also demonstrated that those who had a history of infection and were fully vaccinated (whether disease then vaccinated or vaccinated then disease (i.e., a breakthrough infection) were better able to neutralize the Omicron variant as compared to those who had only a history of disease or had a history of being fully vaccinated. An additional small study investigated the neutralizing activity of sera from convalescent patients, mRNA double vaccinated (BNT162b2 = Pfizer-BioNTech; mRNA-1273 = Moderna), mRNA boosted, convalescent double vaccinated, and convalescent boosted individuals against the original SARS-CoV-2 strain, Beta variant (B.1.351), and Omicron (B1.1.529) variant in a laboratory (in vitro) setting.[42] In the figures depicted below, Figures 1c–1j provide the results of different combinations of sera studied. What would be interpreted as the "best" combination to work against the Omicron variant is the highest level of red dots on the y-axis seen with the B.1.1.529 on the x-axis. For example, Figure 1c shows the results of those individuals with a history of COVID-19 disease. In an oversimplified interpretation, Figure 1c shows that those with a history of COVID-19 disease had no measurable neutralizing activity against the Omicron variant. In Figures 1d and 1e, (2 doses of either Pfizer-BioNTech or Moderna), there is some neutralization against Omicron.

[41] Rossler A., et al SARS-CoV-2 Omicron Variant Neutralization in Serum from Vaccinated and Convalescent Persons, https://www.nejm.org/doi/full/10.1056/NEJMc2119236.

[42] Carreno, J.M. et al. Activity of convalescent and vaccine serum against SARS-CoV-2 Omicron, https://www.nature.com/articles/s41586-022-04399-5.

Those who received a booster (Figure 1f and 1g) had higher levels of neutralization against Omicron compared to the two-dose primary series. Those who had a history of disease and were then vaccinated with a two-dose primary series or a two-dose primary series and a booster (Figures 1h-1j) had better Omicron neutralization. In summary, the study found that neutralizing activity against Omicron "is most impacted in unvaccinated, convalescent individuals and in naïve individuals who acquired immunity through two mRNA COVID-19 vaccine doses" and that "boosted individuals had, at least within the short time after the booster dose, significant protection against symptomatic disease in the range of 75%."[43]

[43] *Id.* at 2.

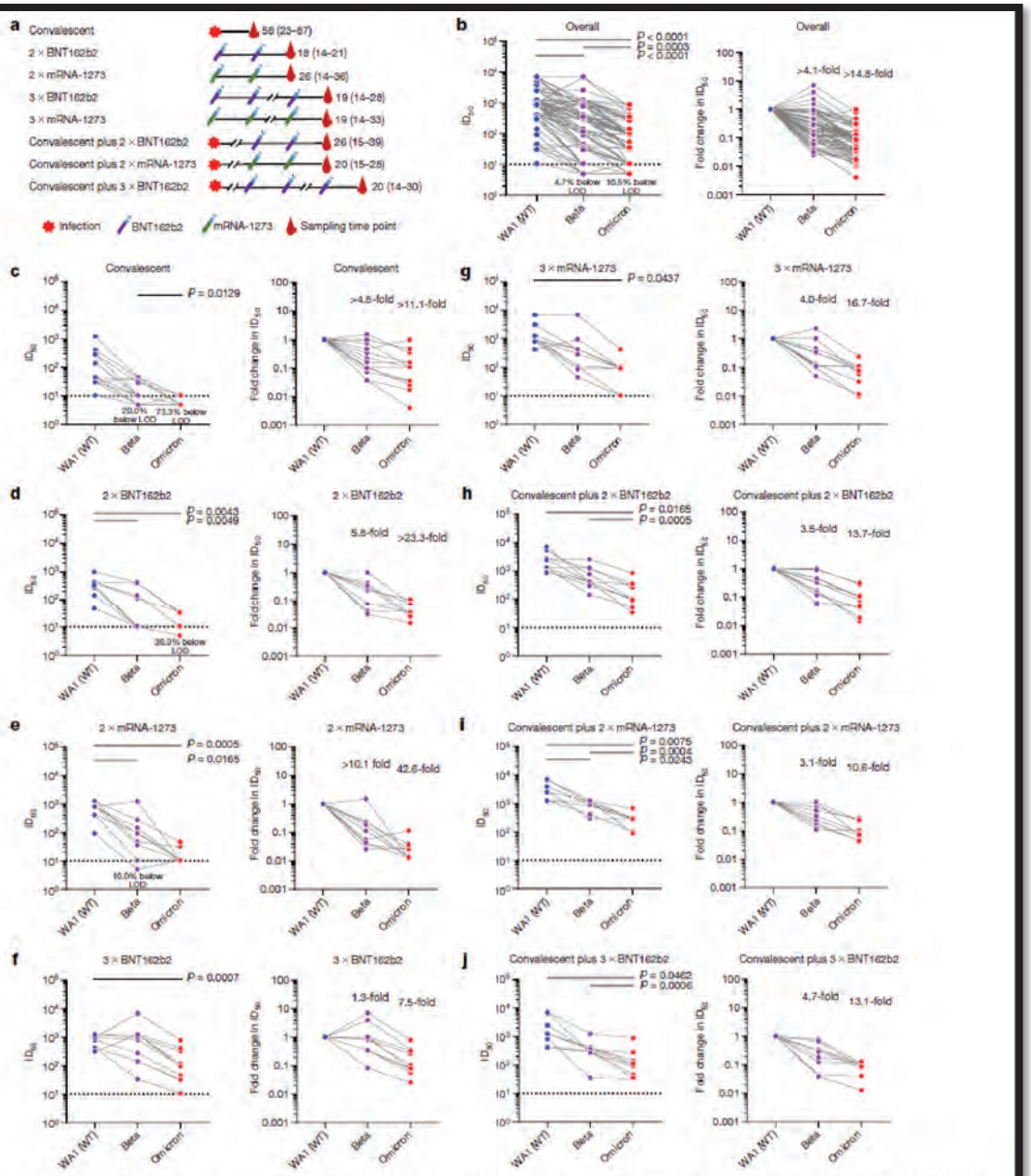
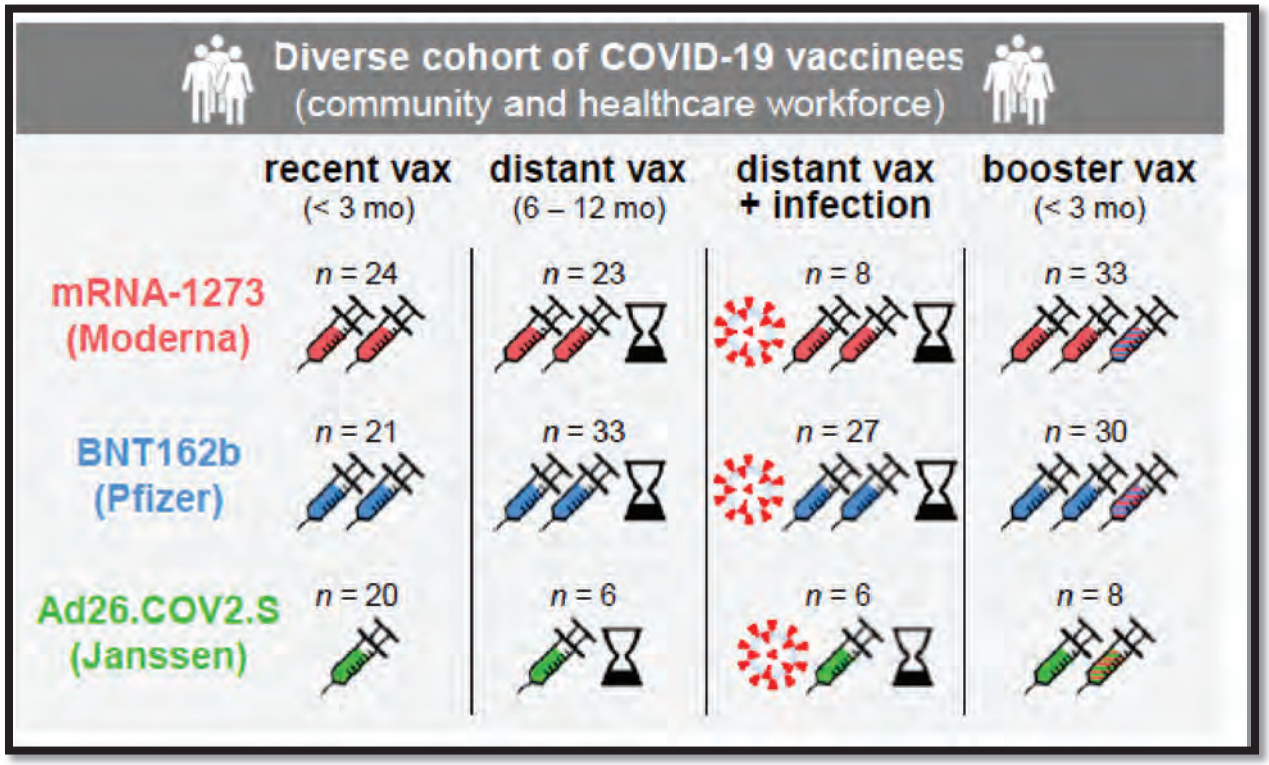


Fig. 1 | Sera from convalescent and vaccinated individuals exhibit strongly reduced neutralizing activity against Omicron compared with wild type SARS-CoV-2. a, Overview of different exposure groups from whom samples were obtained. Further details are provided in Supplementary Tables 1, 2. **b**, Absolute titres (left) and fold reduction (right) for neutralization by all serum samples of wild-type (WA1 (WT)), Beta and Omicron SARS-CoV-2 variants. **c**–**j**, Neutralization of wild-type (WA1 (WT)), Beta and Omicron SARS-CoV-2 variants by sera from convalescent individuals (**c**), after two BNT162b2 vaccinations (**d**), after two mRNA-1273 vaccinations (**e**), after three BNT162b2 vaccinations (**f**), after three mRNA-1273 vaccinations (**g**), from convalescent individuals after two BNT162b2 vaccinations (**h**), from convalescent individuals after two mRNA-1273 vaccinations (**i**) and from convalescent individuals after three BNT162b2 vaccinations (**j**). One-way ANOVA with Tukey's multiple comparisons test was used to compare the neutralization titres; $P < 0.05$ indicated. $n = 85$ (**b**), 15 (**c**), or 10 (**d**–**j**) samples. The dotted line represents the limit of detection (10); negative samples were assigned half the limit of detection (5). Each dot represents a biological replicate and the assays were performed once. Fold change is defined as the geometric mean fold change.

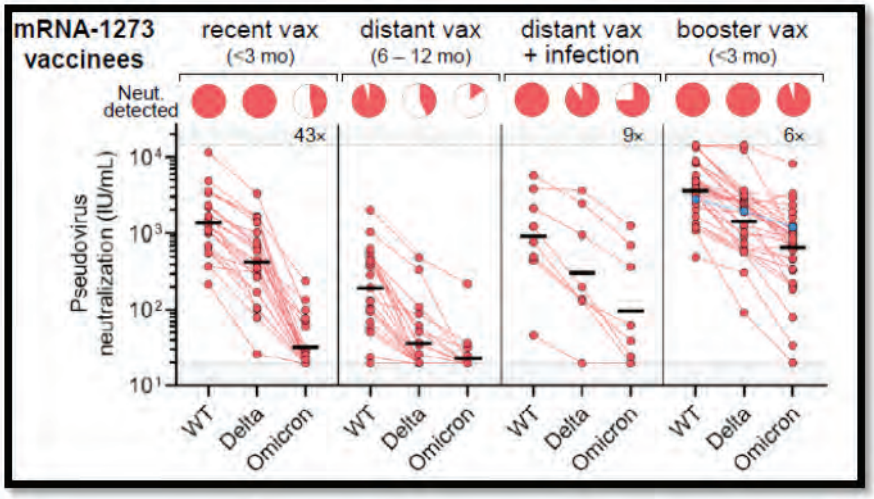
33. An additional study[44] assessed the neutralizing potency of sera from 88 mRNA-1273 (Moderna), 111 BNT162b (Pfizer-BioNTech), and 40 Ad26.COV2.S (Janssen) vaccine recipients against wild-type, Delta, and Omicron COVID-19 variants, based on recent vaccination, distant vaccination (6-12 months), history of infection and distant vaccination, and recent booster vaccination, as depicted below.



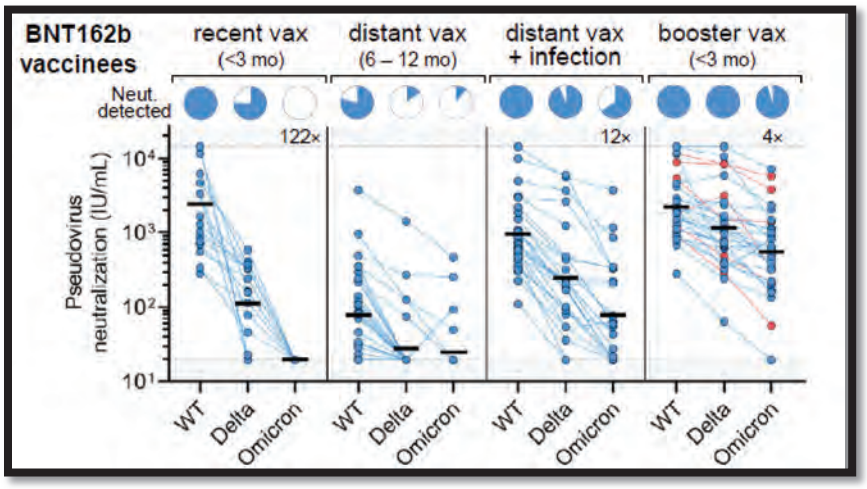
34. Against the Omicron variant, recent (< 3 months) vaccine recipients exhibited a 43-fold lower neutralization than against the wild type (WT) strain. Those with a history of vaccination and infection had a 9-fold decrease in neutralization than WT, whereas those who

[44] Garcia-Beltran WF, et al mRNA-based COVID-19 vaccine boosters induce neutralizing immunity against SARS-CoV-2 Omicron variant. Cell 2022 Feb 3;185(3):457-466.e4. doi: 10.1016/j.cell.2021.12.033.

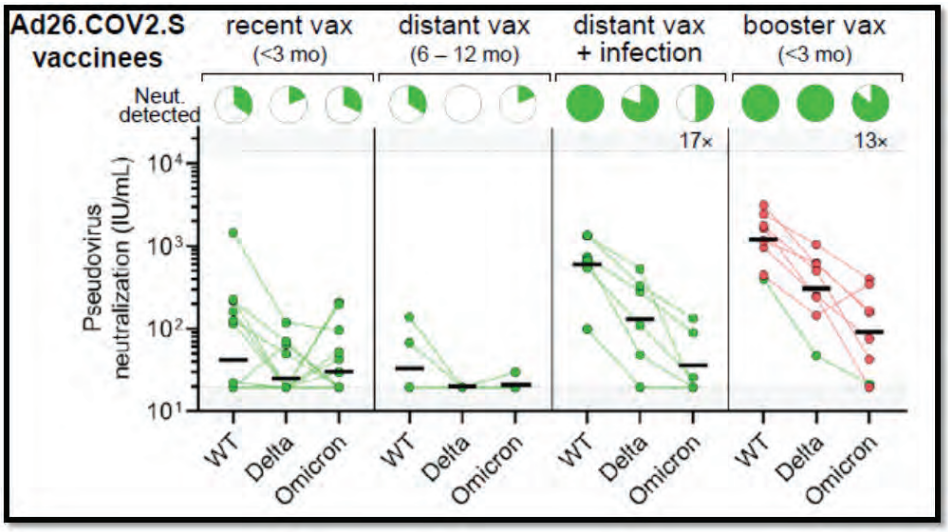
received a booster dose less than 3 months ago had a 6-fold decrease in neutralization compared to WT.



35. Similar results were seen in Pfizer-BioNTech recipients, with the best protection against Omicron seen in those who recently received a booster dose.



36. Of the three vaccines, Janssen recipients had the least neutralization against the Omicron variant, with those who recently received a booster dose demonstrating a 13-fold decrease in neutralization as compared to the WT.



37. Finally, two recent CDC publications described vaccine effectiveness during periods of Delta and Omicron dominance. The first study evaluated the benefit of a third COVID-19 vaccine dose in those who were and were not immunocompromised between August and December 2021. In those who were not immunocompromised vs immunocompromised, vaccine effectiveness (VE) was 82% and 69%, respectively, in those who were fully vaccinated and 97% and 88%, respectively in those who had received 3 doses of COVID-19 vaccine.[45] The second publication reported on the waning 2- and 3-dose effectiveness of mRNA vaccines against COVID-19 associated emergency department (ED) and urgent care (UC) encounters and hospitalizations among adults during Delta and Omicron between August 2021 and January 2022. During the Delta period, those who sought ED or UC care and received 2 doses versus 3 doses of a mRNA vaccine had an overall VE of 80% and 96%, respectively. Of those admitted to the hospital, COVID-19 VE was 85% and 95%, respectively. During the Omicron period, those who

[45] Tenforde MW, et al., Effectiveness of a Third Dose of Pfizer-BioNTech and Moderna Vaccines in Preventing COVID-19 Hospitalization Among Immunocompetent and Immunocompromised Adults – United States, August-December 2021 MMWR Morb Mortal. Wkly Rep 2022;71(4) :118-121. DOI: https://www.cdc.gov/mmwr/volumes/71/wr/mm7104a2.htm.

sought ED or UC care and received 2 doses versus 3 doses of a mRNA vaccine had an overall VE of 41% and 83%, respectively. Those who were admitted to the hospital demonstrated overall VE of 55% and 88%, respectively[46]. Although there was a noticeable decrease in VE during the Omicron period, comparatively mRNA COVID-19 VE is higher than annual influenza vaccine, where VE ranged between 29-48% over the last 5 seasons.[47]

38. In contrast to the above studies, the CDC recently published a study examining the impact of primary COVID-19 vaccination and previous SARS-CoV-2 infection on COVID-19 incidence and hospitalization rates from California and New York.[48] The findings demonstrated that prior to Delta variant, being vaccinated with or without a history of COVID-19 resulted in lower incidence of laboratory-confirmed COVID-19 disease and hospitalizations as compared to those who were unvaccinated with a history of disease. However, after the Delta variant became dominant, those with a history of COVID-19 disease, with or without a history of vaccination, had a lower incidence of laboratory-confirmed COVID-19 disease than those who were vaccinated without a history of COVID-19. Excluded in the study was discussion of severity of COVID-19 disease and outcomes of those who had disease (complications, etc.). CDC concludes with reminding readers that more than 130,000 California and New York residents died from COVID-

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[46] Ferdinands JM, et al. Waning 2-Dose and 3-Dose Effectiveness of mRNA Vaccines Against COVID-19-Associated Emergency Department and Urgent Care Encounters and Hospitalizations Among Adults During Periods of Delta and Omicron Variant Predominance – VISION Network, 10 States, August 2021-January 2022. MMWR Morb Mortal. Wkly Rep 2022;71:1-9. DOI: https://www.cdc.gov/mmwr/volumes/71/wr/mm7107e2.htm.

[47] https://www.cdc.gov/flu/vaccines-work/past-seasons-estimates.html, last accessed March 24, 2022.

[48] Leon TM, Dorabawila V., Nelso L, et al. COVID-19 Cases and Hospitalizations by COVID-19 Vaccination Status and Previous COVID-19 Diagnosis – California and New York, May-November 2021. MMWR Morb Mortal. Wkly Rep 2022;71:125-131. DOI: http://dx.doi.org/10.15585/mmwr.mm7104e1.

19 through November 30, 2021, and that "vaccination remains the safest and primary strategy to prevent SARS-CoV-2 infections, associated complications, and onward transmission."

39. Clinical data of DoD breakthrough rates and hospitalizations as of January 20, 2022, taking into account the prior 6 weeks (where 78.8% of all breakthrough cases were seen) revealed the following results: Of the 1,578,364 active duty fully vaccinated individuals without a booster dose, 116,513 (7.38%) had a breakthrough infection. The hospitalization rate in active duty after full vaccination without a booster was 12 per 100,000 active duty service members. Of those active duty service members who were unvaccinated, the hospitalization rate was 782 per 100,000. Those who were unvaccinated had a higher percentage of critical and severe disease.

40. In summary, unvaccinated persons without a history of COVID-19 are most vulnerable to COVID-19 disease. Vaccination was highly effective against the initial SARS-CoV-2 strain it was developed to protect against. The longer the interval from vaccination, the increased risk for breakthrough disease, although vaccination continues to be protective against severe disease, hospitalization, and death. Vaccination and a history of disease was shown to be less protective than vaccination and booster dose against both the Delta and Omicron variants. Clinically, breakthrough infections during the time of Omicron dominance have been increasingly seen in those fully vaccinated. Hospitalization rates during Omicron dominance in the unvaccinated active duty population were 65 times higher than the hospitalization rate in those fully vaccinated without a booster. CDC states "primary COVID-19 vaccination, additional doses, and booster doses are recommended by CDC's Advisory Committee on Immunization Practices to ensure that all eligible persons are up to date with COVID-19 vaccine, which provides the most

robust protection against initial infection, severe illness, hospitalization, long-term sequelae, and death."[49]

Risks from COVID-19 Vaccination

41. Risks from immunization, including COVID-19 vaccines are rare. CDC provides routine updates on specific adverse events temporally associated with COVID-19 vaccines.[50] CDC updates as of March 21, 2022, include the following:

A. **Anaphylaxis after COVID-19 vaccination is rare** and has occurred in approximately 5 people per million vaccinated in the United States.

B. **Thrombosis with thrombocytopenia syndrome (TTS) after Johnson & Johnson's Janssen (J&J/Janssen) COVID-19 vaccination is rare.** As of March 17, 2022, more than 18.5 million doses of the J&J/Janssen COVID-19 Vaccine have been given in the United States. CDC and FDA identified 60 confirmed reports of people who got the J&J/Janssen COVID-19 Vaccine and later developed TTS. Women 30-49 years of age, especially, should be aware of the rare but increased risk of this adverse event. There are other COVID-19 vaccine options available for which this risk has not been seen.

C. CDC and FDA are monitoring reports of Guillain-Barré Syndrome (GBS) in people who have received the J&J/Janssen COVID-19 Vaccine. GBS is a rare disorder where the body's immune system damages nerve cells, causing muscle weakness and sometimes paralysis. Most people fully recover from GBS, but some have permanent

[49] Leon TM, Dorabawila V., Nelso L, et al. COVID-19 Cases and Hospitalizations by COVID-19 Vaccination Status and Previous COVID-19 Diagnosis – California and New York, May-November 2021. MMWR Morb Mortal. Wkly Rep 2022;71:125-131. DOI: http://dx.doi.org/10.15585/mmwr.mm7104e1.

[50] https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/adverse-events.html, last accessed March 24, 2022.

nerve damage. After more than 18.5 million J&J/Janssen COVID-19 Vaccine doses administered, there have been around 310 preliminary reports of GBS identified in VAERS as of March 17, 2022. These cases have largely been reported about 2 weeks after vaccination and mostly in men, many 50 years and older. CDC will continue to monitor for and evaluate reports of GBS occurring after COVID-19 vaccination and will share more information as it becomes available.

D. **Myocarditis and pericarditis after COVID-19 vaccination are rare.** Myocarditis is inflammation of the heart muscle, and pericarditis is inflammation of the outer lining of the heart. Most patients with myocarditis or pericarditis after COVID-19 vaccination responded well to medicine and rest and felt better quickly. As of March 17, 2022, VAERS has received 2,309 reports of myocarditis or pericarditis among people ages 30 years and younger who received COVID-19 vaccines. Most cases have been reported after mRNA COVID-19 vaccination (Pfizer-BioNTech or Moderna), particularly in male adolescents and young adults. Through follow-up, including medical record reviews, CDC and FDA have verified 1,390 reports of myocarditis or pericarditis.

E. **Reports of death after COVID-19 vaccination are rare**. More than 558 million doses of COVID-19 vaccines were administered in the United States from December 14, 2020, through March 21, 2022. During this time, VAERS received 13,434 reports of death (0.0024%) among people who received a COVID-19 vaccine. FDA requires healthcare providers to report any death after COVID-19 vaccination to VAERS, even if it's unclear whether the vaccine was the cause. **Reports of adverse events to VAERS following vaccination, including deaths, do not necessarily mean that a**

vaccine caused a health problem. A review of available clinical information, including death certificates, autopsy, and medical records, has not established a causal link to COVID-19 vaccines. CDC has identified nine deaths that have been caused by or were directly attributed to TTS following J&J/Janssen COVID-19 vaccination.

42. Additionally, on October 27 2021, the COVID-19 subcommittee of the WHO Global Advisory Committee on Vaccine Safety (GACVS) provided an updated statement regarding myocarditis and pericarditis reported with COVID-19 mRNA vaccines, stating, in part: The GACVS COVID-19 subcommittee notes that myocarditis can occur following SARS-CoV-2 infection (COVID-19 disease) and that mRNA vaccines have clear benefit in preventing hospitalisation and death from COVID-19. Countries should continue to monitor reports of myocarditis and pericarditis following vaccination by age, sex, dose and vaccine brand. Countries should consider the individual and population benefits of immunization relevant to their epidemiological and social context when developing their COVID-19 immunisation policies and programs.[51] In March 2022, Rosenblum, et al., published safety data captured by VAERS reports and v-safe, a new active surveillance system, during the first 6 months of the US COVID-19 vaccination program. During that time, a total of 340,522 VAERS reports were processed following administration of more than 298 million doses of mRNA COVID-19 vaccine. Of these VAERS reports, 313,499 (92.1%) were not serious and managed outside of the hospital setting, 22,527 (6.6%) were serious (defined as inpatient hospitalization, prolongation of hospitalization, permanent disability, life-threatening illness, congenital anomaly or birth defect) and 4,496 (1.3%)

[51] https://www.who.int/news/item/27-10-2021-gacvs-statement-myocarditis-pericarditis-covid-19-mrna-vaccines-updated, last accessed March 24, 2022.

were deaths. Over half of the 4,914,583 v–safe participants self-reported local (i.e injection site pain) and systemic (i.e fever) symptoms, most commonly after dose two. COVID-19 vaccine safety monitoring has been the "most comprehensive in US history". Most reported adverse events captured by VAERS or v-safe were mild and short in duration. The authors report that the mRNA COVID-19 vaccine post-authorization safety profile that was generally consistent with pre-authorization trials and early post-authorization surveillance reports. They conclude by stating "vaccines are the most effective tool to prevent serious COVID-19 disease outcomes and the benefits of immunisation in preventing serious morbidity and mortality strongly favour vaccination."[52]

COVID-19 Antibody Tests

43. As described above, testing to assess for acute SARS-CoV-2 infection or serologic testing to assess for prior infection is not recommended for the purposes of vaccine decision-making. Last updated December 3, 2021, the FDA's EUA Authorized Serology Test Performances[53] lists approximately 90 products, of which all of them had one of the following three statements about immunity interpretation:

[52] Rosenblum HG., et al Safety of mRNA vaccines administered during the initial 6 months of the US COVID-19 vaccination programme: an observational study of reports to the Vaccine Adverse Event Reporting System and v-safe https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(22)00054-8/fulltext.

[53] https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/eua-authorized-serology-test-performance, last accessed March 24, 2022.

A. "You should not interpret the results of this test as an indication or degree of immunity or protection from reinfection."[54]

B. "It is unknown how long antibodies to SARS-CoV-2 will remain present in the body after infection and if they confer immunity to infection. Incorrect assumptions of immunity may lead to premature discontinuation of physical distancing requirements and increase the risk of infection for individuals, their households and the public."[55]

C. "It is unknown how long (IgA, IgM or IgG) antibodies to SARS-CoV-2 will remain present in the body after infection and if they confer immunity to infection. A positive result for XXX test may not mean that an individual's current or past symptoms were due to COVID-19 infection."[56]

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Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

Executed on March 28, 2022, in Falls Church, Virginia

RANS.TONYA.SUE.1081263031 Digitally signed by RANS.TONYA.SUE.1081263031 Date: 2022.03.28 09:32:01 -04'00'

Tonya S. Rans
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[54] https://www.fda.gov/media/146369/download, last accessed March 24, 2022.

[55] https://www.fda.gov/media/138627/download, last accessed March 24, 2022.

[56] https://www.fda.gov/media/137542/download, last accessed March 24, 2022.